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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,069	12/12/2003	Matthias Frericks	920-9US (P10202US)	1279

570 7590 06/06/2006

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PHILADELPHIA, PA 19103

EXAMINER

SMITH, TERRI L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,069

Applicant(s)

FRERICKS ET AL.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,14,15,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-12,14,15,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 April 2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-5, 14-15, and 28-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Holmström et al., U.S. Patent 5,935,158, and in view of Skalsky et al., U.S. Patent 4,784,161, Schulman et al., U.S. Patent 6,844,023, Munshi et al., U.S. Patent 5,683,443 and

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Gibbs et al., *A capacitance enhancement resulting from the interaction of platinum with alkali halides.*

5. With respect to claim 1, Holmström et al. disclose a stimulation electrode comprising an electrically conducting electrode base member (Figs. 1A–1B, element 40, electrically conductive core) formed of at least one metal selected from the group consisting of platinum (column 3, lines 17–18), and wherein an electrode base member is further at least partially coated with an electrically conducting layer comprising at least one material selected from the group consisting of titanium nitride (column 3, lines 19–22). Holmström et al. do not disclose an electrode base member is partially covered with an electrically insulating ceramic layer and is formed of an oxide and/or an oxynitride of at least one metal selected from the group consisting of aluminum and has a thickness of about 1 nm to about 20 μm and an iridium portion of the alloy is k 21 wt. % and a platinum portion of the alloy is > about 100 ppm. However, Skalsky et al. disclose an electrode base member is partially covered with an electrically insulating ceramic layer (Fig. 2, element 60; column 5, lines 47–48), and is formed of an oxide and/or an oxynitride of at least one metal selected from the group consisting of aluminum (column 5, lines 49–50); Schulman et al. disclose a ceramic layer has a thickness of about 1 nm to about 20 μm , shown as “generally, 4–6 layers of alumina, creating a total coating thickness of about 5–10 microns” in column 7 lines 18–19 (Schulman et al. further define micron in column 1, line 44 as 1 micron = 1×10^{-6} meter) (column 3, lines 28–31); Munshi et al. disclose an iridium portion of the alloy is k 21 wt. % (column 24, lines 42–45) and Gibbs et al. discloses a platinum portion of the alloy is > about 100 ppm (page 1393, lines 17–20) to provide an electrode having high pacing impedance, low current drain, low sensing impedance for enhanced sensing and provides lower long-term pacing

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thresholds, to coat and protect microminiature components and devices that are intended to be implanted in living tissue and to maintain electrical leakage of such components within acceptable limits, to significantly reduce the polarization losses and improve the efficiency of the energy transfer through the tissue, and to enhance capacitance and reduce conductance.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Holmström et al. to include an electrode base member is partially covered with an electrically insulating ceramic layer and is formed of an oxide and/or an oxynitride of at least one metal selected from the group consisting of aluminum and has a thickness of about 1 nm to about 20 μm and an iridium portion of the alloy is k 21 wt. % and a platinum portion of the alloy is > about 100 ppm, as taught by Skalsky et al., Schulman et al., Munshi et al. and Gibbs et al. to improve and enhance electrode performance.

6. Regarding claims 3–4, 14–15, Holmström et al., Schulman et al., Munshi et al., and Gibbs et al. disclose the essential features of the claimed invention except for a ceramic layer is arranged on an electrically conducting layer (claim 3), a ceramic layer is arranged adjacent an electrically conducting layer (claim 4), a ceramic layer has a surface closed in itself (claim 14), and a ceramic layer has plurality of independent surfaces (claim 15). However, Skalsky et al. disclose a ceramic layer is arranged on an electrically conducting layer (Fig. 2), a ceramic layer is arranged adjacent an electrically conducting layer on an electrode base member (Fig. 2), a ceramic layer has a surface closed in itself (Figs. 1–2), a ceramic layer has plurality of independent surfaces (Fig. 5) to provide an electrode having high pacing impedance, low current drain, low sensing impedance for enhanced sensing and provides lower long-term pacing thresholds. Therefore, it would have been obvious to one of ordinary skill in the art at the time

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the invention was made to have modified the modified inventions of Holmström et al., Schulman et al., Munshi et al., and Gibbs et al. to include a ceramic layer is arranged on an electrically conducting layer, a ceramic layer is arranged adjacent an electrically conducting layer, a ceramic layer has a surface closed in itself, and a ceramic layer has plurality of independent surfaces, as taught by Skalsky et al. to improve and enhance electrode performance.

7. With respect to claims 5 and 28–29, Holmström et al. disclose an electrically conducting layer is formed of titanium nitride (claim 5) (column 3, lines 19–22), an electrode is implantable in a human (claim 28) and implanted as a cardiac pacemaker electrode (claim 29) (Fig. 3; column 1, lines 7–8).

8. Claim 6–7, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmström et al., Skalsky et al., Schulman et al., Munshi et al., and Gibbs et al., as applied to claim 5 above, and further in view of Gelb et al., U.S. Patent 6,799,076.

9. Regarding claims 6 and 12, Holmström et al., Skalsky et al., Schulman et al., Munshi et al., and Gibbs et al. disclose the essential features of the claimed invention except for an electrically conducting layer is at least partially covered with at least one oxidation protection layer on its side facing away from an electrode base member (claim 6) and a thickness in a range of about 500 nm to about 5 μ m (claim 12). However, Gelb et al. disclose an electrically conducting layer is at least partially covered with at least one oxidation protection layer on its side facing away from an electrode base member (column 2, lines 6–8) and an oxidation protection layer has a thickness in a range of about 500nm to about 5 μ m (column 3, lines 15–16) to achieve low polarization (column 3, lines 46–47). Therefore, it would have been obvious to

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one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Holmström et al., Skalsky et al., Schulman et al., Munshi et al., and Gibbs et al. to include an electrically conducting layer is at least partially covered with at least one oxidation protection layer on its side facing away from an electrode base member, as taught by Gelb et al. to enhance and improve electrode performance.

10. With respect to claims 7 and 10, Holmström et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al. disclose the essential features of the claimed invention except for a ceramic layer is arranged on at least one oxidation protection layer (claim 7) and an oxidation protection layer is formed of at least one element selected from the group consisting of platinum and iridium (claim 10). However, Skalsky et al. disclose a ceramic layer is arranged on at least one oxidation protection layer (Fig. 2) and an oxidation protection layer is formed of at least one element selected from the group consisting of platinum and iridium (column 6, lines 19–21) to provide an electrode having high pacing impedance, low current drain, low sensing impedance for enhanced sensing and provides lower long-term pacing thresholds. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Holmström et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al. to include a ceramic layer is arranged on at least one oxidation protection layer (claim 7) and an oxidation protection layer is formed of at least one element selected from the group consisting of platinum and iridium, as taught by Skalsky et al. to enhance and improve electrode performance.

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11. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmström et al., Skalsky et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al., as applied to claim 6 above, and further in view of Bussard et al., U.S. Patent 4,440,178.

12. Skalsky et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al. disclose the essential features of the claimed invention except for a ceramic layer is arranged adjacent an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member (claim 8) and a ceramic layer is arranged adjacent at least one oxidation protection layer on an electrically conducting layer of titanium nitride (claim 9). However, Bussard et al. disclose a ceramic layer is arranged adjacent an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member (column 2, lines 16–18 and 20; column 4, lines 5–6, 12–13, and 19–20) and a ceramic layer is arranged adjacent at least one oxidation protection layer on an electrically conducting layer of titanium nitride (column 2, line 20; column 4, lines 5–6, 12–13, and 19–20) to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly (column 1, lines 43–46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Holmström et al., Skalsky et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al. to include a ceramic layer is arranged adjacent an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member and a ceramic layer is arranged adjacent at least one oxidation protection layer on an electrically conducting layer of titanium nitride, as taught by Bussard et al. to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly (column 1, lines 43–46).

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holmström et al., Skalsky et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al., as applied to claim 6 above, and further in view of Bolz et al., U.S. Patent 5,609,611.

14. Holmström et al., Skalsky et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al., disclose the essential features of the claimed invention except for an oxidation protection layer is formed of at least one compound selected from the group consisting of oxides, carbides, nitrides, and polymers, and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member. However, Bolz et al. discloses an oxidation protection layer is formed of at least one compound selected from the group consisting of nitrides and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride (Fig. 6) for picking up heart signals for which the low-frequency range is particularly important, especially in the region where the signals are weak (column 8, lines 44–47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Holmström et al., Skalsky et al., Schulman et al., Munshi et al., Gibbs et al., and Gelb et al. to disclose an oxidation protection layer is formed of at least one compound selected from the group consisting of nitrides and wherein at least one oxidation protection layer reduces the impedance of the electrode base member coated with an electrically conducting layer of titanium nitride, as taught by Bolz et al. for picking up heart signals for which the low-frequency

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range is particularly important, especially in the region where the signals are weak (column 8, lines 44-47).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TLS
May 29, 2006

29 May 2006



GEORGE R. EVANSKO
PRIMARY EXAMINER

5/30/6